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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,118	06/28/2000	R. C. Quijano	VENPROO.007C1	6405
27581	7590	08/18/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/605,118	Applicant(s) QUIJANO ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 30-36, 39-41, 54-58, 60-69, 73-79, 81-91, 94-100 and 102-117 is/are pending in the application.
- 4a) Of the above claim(s) 39-41, 54-58, 61, 62, 74-79, 82, 83, 95-100, 103, 104, 116 and 117 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-36, 60, 63-69 and 73 is/are allowed.
- 6) ☒ Claim(s) 84-91, 94, 102 and 105-115 is/are rejected.
- 7) ☒ Claim(s) 81 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the "sealed attachment" by use of stitches is not found in the specification. It is noted that glues or sealants can be used which clearly form a sealed attachment, as mentioned on page 4, line 1 and page 7, lines 1,2. However, no definition is provided and it is not clear that sutures provide a "sealed" attachment. Additionally, the recitation of a "luminal" angle of less than about 30° was not found in the written description. The specification appears to support an angle of 30° for the joined conduits, but it is not evident there is any mention of it referring to a "luminal angle."

### ***Claim Objections***

Claim 81 is objected to because of the following informalities: the claim depends from a canceled claim (70). The claim is not examined on the merits. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 84-91, 102, 105-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Quijano et al. (5500014) in view of Richter et al. '734. Quijano et al. disclose valvular prostheses can be formed from a biological graft with a biological valve for defective blood vessels, col. 5, lines 10-15. Quijano also discloses the configuration depends on the intended use of the prosthesis (col. 8, lines 5-6) and also that valved conduits are needed to repair larger vessels, col. 14, lines 51-59. With respect to claims 88, 112 the valves are fully capable of opening at pressures as low as 1mm Hg and remain sealably closed to withstand backflow pressure greater than 200 mm Hg. Quijano discloses that the tissue is fixed using an aldehyde, col. 10, lines 1-7. Quijano additionally discloses bovine or equine jugular veins can be used, col. 10, lines 12-14. Quijano does disclose the use of sutures for stitching the ends to other tissue, col. 6, lines 43, 55-57. However, Quijano does not disclose joining two segments for a bifurcated section of a damaged vessel. Richter et al. teach to join two conduits together at adjacent inflow ends (Fig. 10) forming a vascular prosthetic where the joined end has a cross-sectional area larger than any of the inflow ends of the conduits (Fig. 11) and the outflow ends can be used for a bifurcation. It would have been obvious to one of ordinary skill in the art to use the teaching of joining two conduits together as taught by Richter with the grafts of Quijano by stitching in order to provide a vascular prosthesis for use in blood vessels comprising branched vessels. Thus in view of the combined teachings the inflow end is suitable for attachment to a heart and the outflow ends are suitable for attachment to pulmonary arteries. It can be construed that joining two of the Quijano conduits as shown in Figs. 16A, 16C would have an angle less than

*about* 30° because the ends are angle cuts and also because Richter shows (Fig. 11) a luminal angle that appears less than about 30°.

Regarding claims 89,90,113,114 Quijano as modified by Richter do not disclose the cross-sectional area of the inflow end of the graft being greater than 22 or 28mm. It would have been an obvious matter of design choice to have an inflow end with a cross-sectional area greater than 22 or 28 mm, since applicant has not disclosed that this diameter provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the dimension taught by Quijano or claims 89,90,113,114 dimensions because both ends perform the same function of providing an increased diameter at the inflow end, considering the typical size of an artery.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 as applied to claim 84 above, and further in view of Ehrenfeld (5156619). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose stitching to form a seam in a single pass for the bifurcated replacement vessel. Ehrenfeld shows (Figs. 3,5) that stitching in the form of single pass is used to attach tubular conduits together forming a graft. Ehrenfeld also teaches that stitching is done such that it is placed on an even continuous suturing surface, col. 3, lines 57-61. It would have been obvious to one of ordinary skill in the art to use single pass stitching as taught by Ehrenfeld as the means

to join graft segments of Quijano as taught by Richter in order to provide means of permanent attachment and reduce any chance of detachment of the joined segments.

### ***Response to Arguments***

Applicant's arguments filed 5/10/04 have been fully considered but they are not persuasive. In response to the remarks that Quijano in view of Richter do not disclose a smooth inner lumen, it must be noted that the joined prosthesis will have a smooth lumen as possible, just as mentioned in Applicant's specification. Quijano's conduit will be as smooth as Applicant's claimed smooth lumen since the same material is used to form the prosthetic device. Regarding the remarks about the sectioned input end being angled, the Examiner is interpreting the limitation to be met since Fig. 11 of Richter is illustrating conduits joined in the same angle degree as Fig. 4 of Applicants.

### ***Allowable Subject Matter***

Claims 30-36,60,63-69,73 are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738

*Brian E. Pellegrino*BRUCE SNOW  
PRIMARY EXAMINER